REMARKS

Favorable reconsideration of applicants' pending claims is respectfully requested in view of the above amendments and following remarks. Following the amendments, claims 2-5, 10, 16, 17 and 19-27 are pending in the application, with claims 19 and 20 being in independent format.

Claim 18 has been cancelled from the application. Claims 2-4, 16, 17, 22-24, 26 and 27 have been amended to remove reference to claim 18.

Independent claim 19 has been amended to state that the liquid seal assembly uses liquid as a sealing medium to prevent air or other fluids from contacting moveable catheter components in the area of a proximal end of a torque tube, to state that the liner surrounds the torque tube as it enters an area of high vacuum in the area of the drive system, to recite an infusion port supplying liquid to the liquid seal assembly at an area of substantially atmospheric pressure, to state that the catheter has a proximal end terminating in the sealing assembly at an aspiration site and extends distally to enclose the torque tube and liner, to clarify that liquid exits the flood space at an intersect area and directly enters the aspiration lumen at the intersect area, and to correct a minor typographical error. It is urged that support for these amendments may be found, for example, in paragraphs 0014, 0022, 0026, 0031, 0030 and 0044 of the published application.

Independent claim 20 has been amended to clarify that the sealing assembly comprises a housing enclosing at least a proximal portion of the torque tube and a sealing site, a liner forming a flood space, and an infusion port that provides liquid to the flood space, and also to state that the catheter terminates in the sealing assembly at an aspiration site and extends distally beyond the intersect area to enclose the liner, whereby liquid enters the flood space formed by the liner at the sealing site and creates a liquid seal around the torque tube to prevent ingress of air, the liquid exiting the flood space at the intersect area where it directly enters the aspiration lumen. Support for these amendments may be found, for example, in paragraphs 0030, 0044, 0022 and 0049 of the published application and in Figs. 1 and 2 as originally filed.

It is urged that support for all the above amendments may be found throughout the specification and drawings as originally filed, and that none of the amendments constitute new

matter. Applicants specifically reserve the right to pursue claims to any subject matter cancelled from the claims by the above amendments in one or more related applications.

Claim rejections under 35 USC §102

Claims 2/18, 2/18, 4/18, 16/18, 17/18 and 26/18 stand rejected under 35 USC §102(b) as being anticipated by Zacca, et al. (US 5,217,474).

While applicants do not acquiesce in this rejection and strongly disagree with the Examiner's position, claim 18 has been cancelled in order to expedite allowance of the application.

Claim rejections under 35 USC §103

Claims 2/19-5/19, 2/20-5/20, 10, 16/19, 16/20, 17/19, 17/20, 19, 20, 22/19, 22/20, 23/19, 23/20, 26/19 and 26/20 stand rejected under 35 USC §103(a) as being unpatentable over Zacca, et al. (US Patent 5,217,474) in view of Mische et al. (US Patent 5,490,859). This rejection is respectfully traversed.

The present application discloses and claims a liquid seal assembly that provides an air-tight, substantially friction-free seal around a high speed rotational driveshaft in proximity to powerful aspiration. Providing a reliable, air-tight, low (or no) friction seal around a high speed rotational driveshaft is particularly challenging when the driveshaft is not solid and is provided, for example, as a coiled structure. Conventional sealing mechanisms, such as O-rings, bushings and bearings, are typically used to seal a drive shaft, but these sealing mechanisms are prone to leakage and frictional heating as the drive shaft rotates, particularly at high rotational rates, during operation of the device. The pending claims are directed to devices that use liquid as a sealing medium at sealing sites, thereby eliminating the need to use conventional sealing mechanisms such as O-rings, bushings and bearings.

Specifically, independent claim 19 is drawn to an aspirating catheter device having a liquid seal assembly that uses liquid as a sealing medium to prevent air or other fluids from contacting moveable catheter components in the area of a proximal end of a torque tube. The device comprises a torque tube operably connected to a drive system for rotation, a liner

surrounding the torque tube as it enters an area of high vacuum in the area of the drive system to form a liquid flood space between the liner and the torque tube, the liner extending longitudinally less than the axial length of the torque tube and terminating distally at an intersect area, an infusion port supplying liquid to the liquid seal assembly at an area of substantially atmospheric pressure, and a catheter having a proximal end terminating in the sealing assembly at an aspiration site and extending distally to enclose the torque tube and the liner, wherein the catheter extends distally beyond the intersect area with respect to an operator of the device and forms an aspiration lumen between the catheter and the liner. As stated in the claim, liquid drawn into the flood space during operation of the catheter system exits the flood space at the intersect area and enters the aspiration lumen *directly at the intersect area*. In other words, liquid exits the flood space formed by the liner and is drawn into the aspiration lumen without exiting the device.

Independent claim 20 is drawn to a medical device comprising: (a) a rotatable torque tube operably connected to a drive system for rotation; (b) a sealing assembly comprising a housing enclosing at least a proximal portion of the torque tube and a sealing site, a liner surrounding the torque tube and forming a flood space extending longitudinally from the sealing site along at least a portion of the torque tube to a distal terminal end of the liner at an intersect area, and an infusion port providing application of liquid to the flood space at the sealing site during operation of the device; and (c) a catheter terminating in the sealing assembly at an aspiration site and extending distally beyond the intersect area to enclose the liner and forming an aspiration lumen between the catheter and the liner, whereby, during operation of the medical device, liquid enters the flood space formed by the liner at the sealing site and creates a liquid seal around the torque tube to prevent ingress of air, the liquid exiting the flood space at the intersect area, where it directly enters the aspiration lumen.

The Examiner asserts that Zacca et al. disclose a medical device comprising: a torque tube operably connected to a drive system for rotation; a liner (14) surrounding the rotatable torque tube to form a liquid flood space between the liner and the torque tube, the liner extending longitudinally less than the axial length of the torque tube and terminating at an intersect area. The Examiner also asserts that "Zacca et al. disclose an additional catheter or guide catheter enclosing the torque tube (col. 7, ln. 51-58)" but notes that Zacca et al. fail to disclose that the

guide catheter is an aspiration catheter. The Examiner further asserts that Mische et al. disclose an aspiration catheter and that it would have been obvious to provide negative pressure to the guide catheter of Zacca et al. in order to remove particulate matter from the body as suggested by Mische et al.

Zacca et al. describe an atherectomy device having an expandable tip. The catheter described at col. 7, lines 51-55 of Zacca et al. is a guide catheter that can be employed to introduce the device of Zacca et al. into a body lumen. Such catheters are commonly employed in the art to position medical devices in a body lumen prior to operation of the device, as described at col. 7, lines 12-50 of Zacca et al., and do not form part of such medical devices.

Mische et al. describe an intravascular material removal device including an expandable material removal element. At col. 26, line 61 to col. 26, line 4, Mische et al. state that a negative pressure may be provided through a guide catheter in order to create a pressure differential within a vascular lumen and force fluid and occlusion particulate proximally through the guide catheter and out of the patient's body. However, at col. 14, line 61- col. 15, line 3, Mische et al. teach that it is desirable to limit back flow of blood and other bodily fluids though a lumen formed between the guide catheter and removal device, e.g. by the use of a fluid seal (col. 14, line 61 – col. 15, line 3).

As recited in both independent claim 19 and independent claim 20, the catheter forming part of the claimed device terminates (proximally) in the sealing assembly at an aspiration site and extends distally beyond an intersect area where the flood space formed by the liner terminates. The arrangement of applicants' claimed components provides that liquid drawn into the flood space in the area of the drive system seals the area of the proximal end of the torque tube without requiring bearings, bushings, O-rings or other conventional sealing components, and prevents air or other fluids from contacting moveable catheter components during operation. This liquid is drawn down the liquid flood space and exits at the intersect area which is *inside* the aspiration lumen formed by the catheter, directly entering the aspiration lumen. This feature of the claimed invention is neither taught nor suggested by either Zacca et al. or Mische et al. or any combination of their teachings. Applicants note, furthermore, the guide catheter of Zacca et al.

and Mische et al. would not have a proximal end terminating in a sealing assembly as clearly recited in independent claims 19 and 20.

It is therefore submitted that neither Zacca et al. nor Mische et al., taken either singly or in combination, teach or suggest the presently claimed invention, and that the rejection of claims 2/19-5/19, 2/20-5/20, 10, 16/19, 16/20, 17/19, 17/20, 19, 20, 22/19, 22/20, 23/19, 23/20, 26/19 and 26/20 under 35 USC §103(a) can be properly withdrawn.

Claims 21/18 and 27/18 stand rejected under 35 USC §103(a) as being unpatentable over Zacca et al. in view of Keith et al. (US 5,938,670). As noted above, claim 18 has been cancelled from the application, thereby rendering this rejection moot.

Claims 21/19, 21/20, 27/19 and 27/20 stand rejected under 35 USC §103(a) as being unpatentable over Zacca et al. (US Patent 5,217,474) in view of Mische et al. (US Patent 5,490,859), and further in view of Keith et al. (US 5,938,670). This rejection is respectfully traversed.

The disclosures of Zacca et al. and Mische et al. are discussed above. The Examiner states that Keith et al. disclose that a smaller gap provides more resistance to fluid flow and asserts that it would have been obvious to dimension the diameter and length of the liner of Zacca et al. to provide more resistance to fluid flow as taught by Keith et al. However, Keith et al. do not overcome the deficiencies of Zacca et al. and Mische et al. discussed above.

Applicants submit that neither Zacca et al., Mische et al. or Keith et al., taken either singly or in combination, would have rendered the subject matter of claims 21/19, 21/20, 27/19 and 27/20 obvious to one of skill in the art, and that this rejection can thus be properly withdrawn.

Claims 22/18 and 23/18 stand rejected under 35 USC §103(a) as being unpatentable over Zacca et al. As noted above, claim 18 has been cancelled from the application, thereby rendering this rejection moot.

Claims 24/19, 24/20, 25/19 and 25/20 stand rejected under 35 USC §103(a) as being unpatentable over Zacca et al. in view of Mische et al, and further in view of Milo (US 6,258,052) and Machold et al. (US 4,976,720). This rejection is respectfully traversed.

The disclosures of Zacca et al. and Mische et al. are discussed above. The Examiner asserts that Milo discloses the use of a polyimide tube and that Machold et al. disclose a polyimide tube having a lubricious coating. However, neither Milo nor Machold et al. overcome the deficiencies of Zacca et al. and Mische et al. discussed above.

It is urged that neither Zacca et al., Mische et al., Milo or Machold et al. teach or suggest the subject matter recited in claims 24/19, 24/20, 25/19 and 25/20, and that the rejection of these claims under 35 USC §103(a) may thus be properly withdrawn.

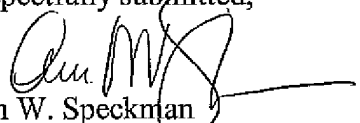
Concluding Remarks

Every effort has been made to put the pending claims in condition for allowance. Early reconsideration and allowance of the pending claims is respectfully requested.

A request for a one month extension of time, extending the deadline for response to October 9, 2009, is submitted herewith.

The Examiner is invited to telephone Janet Sleath or Ann Speckman at 206.382.1191 if she has questions or if a discussion of the pending claims or the prior art references relied upon for rejection would be beneficial.

Respectfully submitted,



Ann W. Speckman
Registration No. 31,881

Date: October 9, 2009

SPECKMAN LAW GROUP PLLC

20601